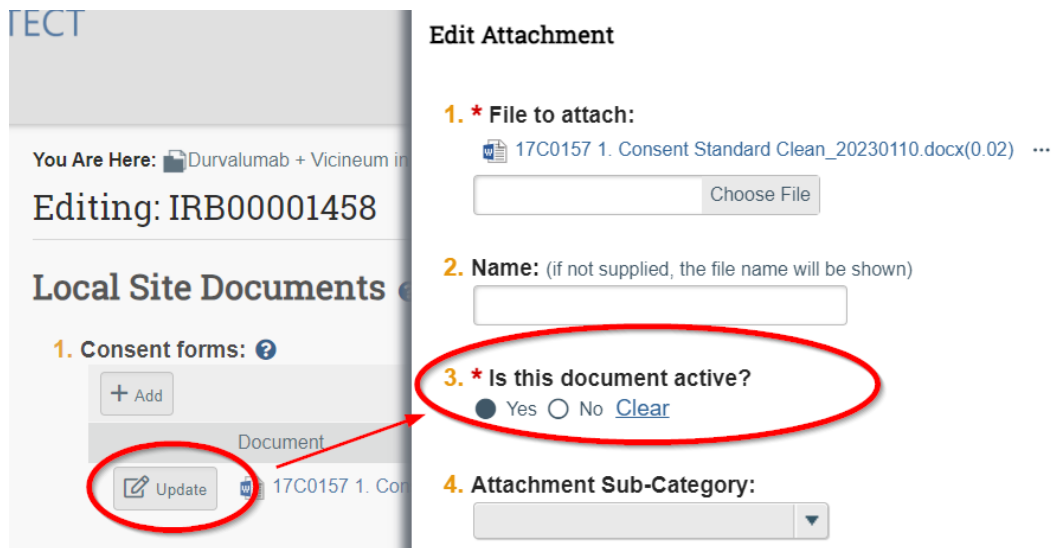
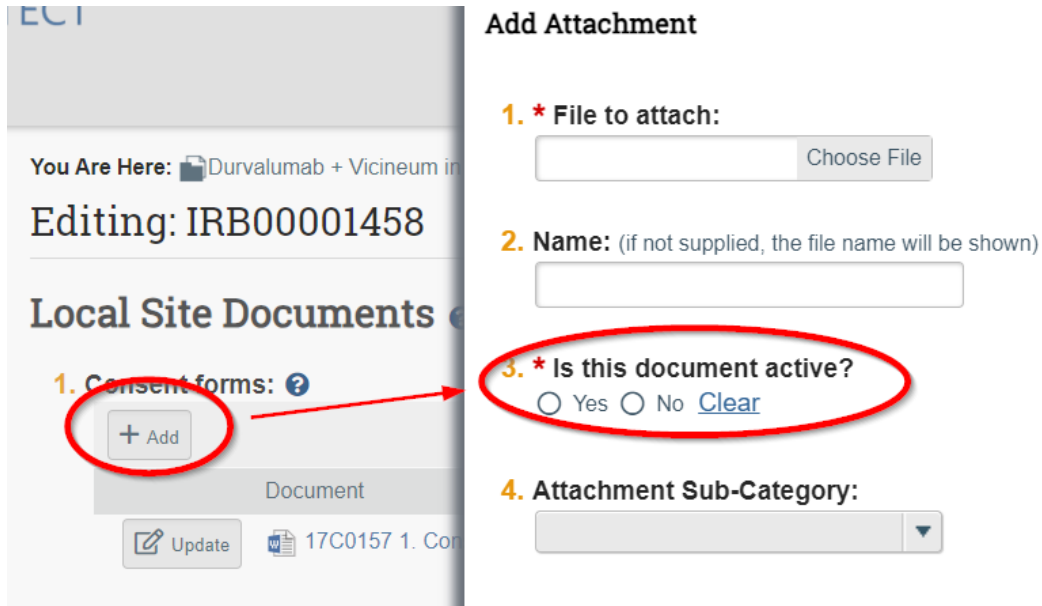


PROTECT Tip Sheet: Marking documents as *Active (yes/no)*

Summary of Active Documents functionality:

In the IRB study form and Scientific Review form, for every document type, there is a new mandatory question when you ADD new documents or use the 'UPDATE' button on a MOD. This new question asks: *Is this document active? Yes/No*. See screenshots below:



What is 'Active':

Documents that are "Active" are defined as those that are currently being used in the study. Documents that are no longer "Active" (inactive) are those that have been retired and are no longer in use, e.g., a

consent document for a cohort that has been completed or a recruitment material that is no longer being used. For those types of documents, you should select “no” (not active) on this new question.

Where PROTECT displays this label:

The status of each document (*Is Active? Yes/No*) will be displayed on the *Documents* tabs of the IRB and SRC project workspaces as well so users may easily identify these as such.

NOTE: All documents on existing active studies in PROTECT have already been marked as Active so you will NOT have to go back and answer this new question for each existing document. If, however, the study team wants to Update the ‘Active: Yes/No’ status for the docs during a MOD, you may revise that answer for any document on the form if the application is in an editable state.

History	Documents	Reviews	Follow-on Submissions			
Study Documents						
Study Related Documents						
Draft						
Document	Category	Is Active?	Final	Last Finalized	Document History	
WSUIRB_IRB-21-09-4030.pdf	Other	yes			History	
001769.Main Site Assent_13-17.Initial Review.02242022.doc	Consent Form	yes			History	
001769.Main Site Oral Assent_7-12.Initial Review.02242022.docx	Consent Form	yes			History	
001769.Main Site Parental Permission.Initial Review.02242022.doc	Consent Form	yes			History	
001769.Main Site Consent.Initial Review.02242022.doc	Consent Form	yes			History	
001769.Sponsor_Core Protocol.Initial Review.02242022.docx	IRB Protocol	yes			History	
Site Related Documents						
Draft						
Document	Category	Is Active?	Final	Last Finalized	Document History	
001769.External IRB Approval.Initial Review.02242022.pdf	External IRB Approval Letter	yes			History	
001769.NIH Protocol Addendum.Initial Review.02242022.docx	NIH Addendum	yes			History	
IC-Specific Scientific Review Forms:						
Document						
Document	Category	Active	Date Modified	Document History		
SheikhBahaei_CV_062023.docx(0.01)	SRC: Other	yes	6/8/2023	History		
NIH Addendum:						
Document						
Document	Category	Active	Date Modified	Document History		
001769.External IRB Approval.Initial Review.02242022.pdf(0.01)	External IRB Approval Letter	yes	6/6/2023	History		
001769.NIH Protocol Addendum.Initial Review.02242022.docx(0.01)	NIH Addendum	yes	6/6/2023	History		

The status of each document will also be displayed in the IRB, SRC, and RSC forms wherever documents appear.

Local Site Documents

1. Consent forms:

+ Add						
Document	Category	Active	Date Modified	Document History		
Update 17C0157 1. Consent Standard Clean_20230110.docx(0.02)	Consent Form	yes	2/1/2023	History		

2. Recruitment materials: (add all material to be seen or heard by subjects, including ads)

+ Add						
Document	Category	Active	Date Modified	Document History		
There are no items to display						

3. Other attachments:

+ Add						
Document	Category	Active	Date Modified	Document History		
Update 17C0157 Cover Memo_20230110.docx(0.01)	Summary of Changes (Modification - ONLY)	yes	2/6/2023	History		

Finalize Documents: (IRB Staff Only)

When the IRB Staff run the Finalize Documents activity, they will notice that there is now an Active column displaying these values.

Finalize Documents



Select the submission's supporting documents that should be finalized and have a permanent record created for them. Finalizing creates a PDF copy of each document and stamps it with the watermark for its specific category.

Approve	Draft	Updated in Modification	Category	Active	Final	Last Finalized
<input type="checkbox"/>	000118_Consent-Standard_Spanish_21DEC2022.docx	Yes	Consent Form	yes		
<input type="checkbox"/>	000118_Summary of Changes Table_30MAY2023.docx	Yes	Summary of Changes (Modification - ONLY)	yes		
<input type="checkbox"/>	000118_COVIDQuestionnaireClean_30MAY2023.docx	Yes	Study Instrument(s) - e.g. survey/questionnaire	yes	000118_COVID-19.Questionnaire21Sept2022.pdf	1/13/2023 2:25 AM
<input type="checkbox"/>	000118_Letter for COVID study_clean_30MAY2023.docx	Yes	Recruitment Materials	yes	000118_Letter for COVID studyClean_19DEC2022.pdf	1/13/2023 2:25 AM
<input type="checkbox"/>	000118_ProtocolClean_30MAY2023.docx	Yes	IRB Protocol	yes	000118_ProtocolClean_03FEB2023.pdf	2/21/2023 10:52 AM
<input type="checkbox"/>	000118_Spanish_Certification of Accuracy_18APR2023.pdf	Yes	Consent: Translation Certification	yes		
<input type="checkbox"/>	000118_ConsentClean_21DEC2022.docx	No	Consent Form	yes	000118_ConsentClean_21DEC2022.pdf	1/13/2023 2:25 AM